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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,114	08/18/1998	IAN ASHLEY PRICE	P8129-8004	7439

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ARENT, FOX, KINTNER, PLOTKIN & KAHN, P.L.L.C.
1050 CONNECTICUT AVENUE, N.W.
SUITE 600
WASHINGTON, DC 20036-5339

EXAMINER
BERMAN, ALYSIA

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/125,114	Applicant(s) PRICE, IAN ASHLEY	
	Examiner Alysia Berman	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *11-15,20-25 and 32-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,16-19,26-31 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *25* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Receipt is acknowledged of the amendment filed December 14, 2001 and the supplemental response filed January 29, 2002. Claims 1, 11, 16, 20, 26 and 27 have been amended. Claims 1-38 are pending.

Election/Restrictions

2. Applicant's election of Group I, claims 1-10, 16-19, 26-31 and 38, in Paper No. 26 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 11-15, 20-25 and 32-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 26.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-10, 16-19, 26-31 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The claims are vague and indefinite because it is unclear what Applicant intends to claim in homogeneous admixture with what. Is it the dosage form or the ibuprofen medicament that Applicant intends to have in homogeneous admixture with the carrier material? If Applicant intends for the ibuprofen medicament to be in homogeneous admixture with the carrier material, amendment of the claim inserting, "a homogeneous admixture of" after "comprising" in line 2 along with deletion of "in homogeneous admixture with" at lines 3-4 of claim 1 would overcome this rejection.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-10, 16-19, 26-31 and 38 rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,380,535 (535).

US '535 is directed to chewable compositions for oral delivery of unpalatable drugs (abstract). Chewable products in the form of compressed tablets (claim 10) or uncompressed powder are disclosed at column 2, lines 37-39. The composition comprises an unpalatable drug, a lipid and various other conventional excipients and additives. For mannitol and lactose, see column 6, lines 2-6. For microcrystalline cellulose, see column 7, lines 26-28. These are Applicants preferred compressible fillers of instant claims 8 and 31. For sodium bicarbonate, see column 6, lines 16-28. For sodium starch glycolate, croscarmellose sodium and cross-linked polyvinylpyrrolidone (crospovidone), the disintegrating components of instant claims 9 and 30, see column 6, lines 42-68.

A compressed tablet also comprising lubricants and flow aids is disclosed at column 7, lines 20-30. An ibuprofen composition comprising 0.5-40 wt.% ibuprofen, 25-75 wt.% granulating agent (mannitol and lactose compressible fillers), 1-30 wt.% dispersal agent (sodium starch glycolate and croscarmellose sodium) and 0.5-7 wt.% lubricant is disclosed at column 8, lines 1-36. US '535 0.2-10 wt.% of inert diluents such as flavorants and sweeteners (col. 8, lines 20-30). See also Examples 3 and 5 and claims 3 and 17 for ibuprofen, sodium bicarbonate, compressed tablets and mannitol.

US '535 discloses a powder that can be compressed into a tablet comprising ibuprofen, a compressible filler, a disintegrant, sodium bicarbonate, lubricants and flow aids. It does not explicitly disclose a salt of ibuprofen or a solid formulation having a layer as in instant claim 26.

US '535 does disclose at column 4, lines 3-22 that ibuprofen or other drugs may be used in the compositions. Additionally, salts of the drugs may be used. US '907 discloses a bilayered tablet comprising a layer that contains a non-steroidal anti-inflammatory (NSAID) or salt thereof such as ibuprofen (abstract). US '907 discloses sodium salts of various NSAIDs and alkali metal salts at column 2, lines 16-33.

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the tablet of US '535 in a layered form using the sodium salt of ibuprofen as taught by US '907 in order to provide a dosage form for administering more than one pharmaceutically active substance.

11. Claims 1-10, 27-31 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,380,535 (535) in combination with US 5,262,179 (179).

US '535 discloses all the limitations of the claims as stated in the 35 U.S.C. 103(a) rejection above. It does not explicitly teach ibuprofen salts.

US '179 teaches that ibuprofen salts have an unpleasant taste and, therefore, it is advantageous to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form (abstract). For the sodium salt of ibuprofen, see column 3, lines 26-30.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sodium salt of ibuprofen as taught by US '179 into the dosage form of US '535 with the expectation of masking the taste of the sodium salt of ibuprofen.

12. The limitations of claims 27 and 30 reciting "up to" a certain amount of components does not add required limitations to the claims. The phrase "up to" includes zero as a lower limit. *In re Mochel*, 470 F2d. 638, 176 USPQ 194 (CCPA 1974). Additionally, claim 28 includes zero as a lower limit. Therefore, the claims as written do not require an diluent or lubricant.

13. The limitations directed to properties of the dosage form such as crushing strength and disintegration time art not given patentable weight over the prior art compositions. The composition resulting from the combination of the prior art having the same components as instantly claimed would be expected to exhibit the same properties. Burden is shifted to Applicant to show that the composition resulting from the combination of the prior art does not exhibit the same properties as instantly claimed. Additionally, the limitation directed to a racemic mixture of ibuprofen is not given patentable weight. It is well established in the art that chiral chemical compounds exist as racemic mixtures of enantiomers. Because the references are silent as to the optical activity of the ibuprofen, it is the examiner's position that they encompass the racemic mixture and/or a single enantiomer.

Response to Arguments

14. Applicant's arguments filed December 14, 2001 have been fully considered but they are not persuasive.

15. In response to applicant's argument that the objectives of the references are entirely different from the objective of applicant, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

16. Applicant argues that there is nothing in US '535 that would encourage one of ordinary skill in the art to make the selections necessary to produce a dosage form having the components instantly claimed. US '535 clearly teaches a compressed dosage form containing ibuprofen, a compressible filler, a disintegrant and various other components as desired (col. 8, lines 1-36). US '535 also teaches at column 6, lines 16-28 that it is preferred to add a buffering agent such as sodium bicarbonate to the dosage form. This disclosure clearly teaches the combination of components as instantly claimed.

17. Applicant argues that one of ordinary skill in the art would not have expected to obtain the crushing strength and disintegration time instantly. Applicant has not provided any comparative data showing unexpected results of crushing strength over the prior art. Mere statements or allegations by Applicant or his attorney are not sufficient to evaluate unexpected results. US '535 clearly teaches that one objective of the reference is rapid disintegration. It is the examiner's position that this disclosure of rapid

disintegration encompasses a disintegration time as instantly claimed, absent evidence to the contrary. Additionally, a composition containing the same components as instantly claimed would be expected to exhibit the same properties. Therefore, the crushing strength and disintegration time instantly claimed are not unexpected.

18. It is noted that claims 1 and 26 do not require the same limitations. Claim 1 is drawn to a compressed dosage form and claim 26 is drawn to a solid formulation having a layer.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached during core hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3704 or 703-305-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

Alysia Berman
Patent Examiner
February 7, 2002

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600